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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,599	08/01/2003	Min Hu	HU0201	5854
	7590	06/02/2004	EXAMINER	
Bo-In Lin 13445 Mandoli Drive Los Altos Hills, CA 94022			HENRY, MICHAEL C	
			ART UNIT	PAPER NUMBER

1623

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/632,599	HU, MIN	
	Examiner	Art Unit	
	Michael C. Henry	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 1-12 and 15-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The following office action is a responsive to an amendment filed on 5/18/04 in which a election was made without traverse to prosecute the invention of Group II, claims 13 and 14.

The response has the following effect:

1. Claims 13 and 14, the invention of Group II are prosecuted by the examiner.

Claims 1-12 and 15-23 are withdrawn.

Claims 1-23 are pending in application

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Polarek et al. (US 5,510,328) in view of Arnold (US 5,766,631)

In claim 13, applicant claims "A method of promoting wound healing in a subject, said method comprising administering to said subject a composition comprising: a glycosaminoglycan structure, wherein said glycosaminoglycan structure comprises a core of free glycosaminoglycan, a layer of crosslinked glycoanminoglycan surrounding said core; a charged molecule surrounding said crosslinked glycosaminoglycan layer; and an excipient."

Polarek et al. disclose a method of promoting wound healing (by reducing and inhibiting wound contraction) in a subject, said method comprising administering to said subject a

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composition comprising: a polypeptide, decorin (a charged molecule) and a pharmaceutical carrier (see abstract and claim 1). In addition, Polarek et al. disclose that a basic polyamino acid such as polyarginine or polylysine (polypeptides) can be used to reduce or inhibit wound contraction, and that polyarginine and polysine support cell attachment on solid supports based on the positive charge resulting from the basic polyamino acid coating (see col. 4, lines 53-64). This implies a basic polyaminoacid such as polysine when used as a coating for a composition (such as the coating or layer surrounding applicant's composition), would attach to cells (such as cells of a wound). It should be noted that the examiner considers a pharmaceutical carrier an excipient. Furthermore, the use of art recognized excipients in combination with active ingredients is well within the purview of a skilled artisan

Arnold discloses wound implant materials (materials that would promote wound healing) which comprises a microsphere and/or a matrix in which the microsphere and the matrix can be a glycosaminoglycan (hyaluronic acid) and a cross-linked glycosaminoglycan (cross-linked hyaluronic acid) (see abstract and example 1, lines 27-51).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Polarek et al. and Arnold, to have used the method of Polarek et al. to administer a composition comprising a combination of a glycosaminoglycan (hyaluronic acid), a cross-linked glycosaminoglycan (cross-linked hyaluronic acid) and a charged basic polypeptide molecule such as polylysine to promote wound healing, since the combination of compounds that are used to treat the same diseases or conditions are well known in the art. More specifically, it is obvious to combine individual compositions taught to have the same utility to

form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

One having ordinary skill in the art would have been motivated in view of Polarek et al. and Arnold, to have used the method of Polarek et al. to administer a composition comprising a combination of a glycosaminoglycan (hyaluronic acid), a cross-linked glycosaminoglycan (cross-linked hyaluronic acid) and a charged basic polypeptide molecule such as polylysine to promote wound healing, because a skilled artisan would reasonably be expected to prepare a composition comprising a combination of the compounds taught by Polarek et al. and Arnold, to promote wound healing based on type and/or severity of the wound.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Polarek et al. (US 5,510,328) in view of Arnold (US 5,766,631)

In claim 14, applicant claims "A method for treating a glycosaminoglycan-mediated condition in a subject, said method comprising: administering to said subject a composition comprising: a glycosaminoglycan structure, wherein said glycosaminoglycan structure comprises a core of free glycosaminoglycan, a layer of crosslinked glycosaminoglycan surrounding said core; a charged molecule surrounding said crosslinked glycosaminoglycan layer; and an excipient."

Polarek et al. disclose a method for treating a glycosaminoglycan-mediated condition (by reducing and inhibiting wound contraction) in a subject, said method comprising administering to said subject a composition comprising: a polypeptide, decorin (a charged molecule) (see abstract and claim 1) and a pharmaceutically acceptable carrier. In addition, Polarek et al. disclose that a basic polyamino acid such as polyarginine or polylysine (polypeptides) can be

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used to reduce or inhibit wound contraction, and that polyarginine and polysine support cell attachment on solid supports based on the positive charge resulting from the basic polyamino acid coating (see col. 4, lines 53-64). This implies a basic polyaminoacid such as polysine when used as a coating for a composition (such as in applicant composition) would attach to cells (such as cells of a wound). It should be noted that the existence of wound in a subject is the existence of a glycosaminoglycan-mediated condition in a subject and the examiner considers a pharmaceutical carrier an excipient. Furthermore, the use of art recognized excipients in combination with active ingredients is well within the purview of a skilled artisan.

Arnold discloses wound implant materials (materials that would promote wound healing) which comprises a microsphere and/or a matrix in which the microsphere and the matrix can be a glycosaminoglycan (hyaluronic acid) and a cross-linked glycosaminoglycan (cross-linked hyaluronic acid) (see abstract and example 1, lines 27-51).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Polarek et al. and Arnold, to have used the method of Polarek et al. to administer a composition comprising a combination of a glycosaminoglycan (hyaluronic acid), a cross-linked glycosaminoglycan (cross-linked hyaluronic acid) and a charged basic polypeptide molecule such as polylysine to promote wound healing, since the combination of compounds that are used to treat the same diseases or conditions are well known in the art. More specifically, it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

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One having ordinary skill in the art would have been motivated in view of Polarek et al. and Arnold, to have used the method of Polarek et al. to administer a composition comprising a combination of a glycosaminoglycan (hyaluronic acid), a cross-linked glycosaminoglycan (cross-linked hyaluronic acid) and a charged basic polypeptide molecule such as polylysine to promote wound healing, because a skilled artisan would reasonably be expected to prepare a composition comprising a combination of the compounds taught by Polarek et al. and Arnold, to promote wound healing based on type and/or severity of the wound.

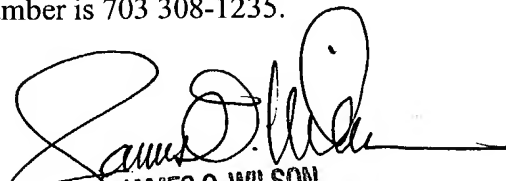
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

MCH

May 28, 2004.


JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600